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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,887	03/30/2004		Edward Ashton	116741-00238 1329	
27557	7590	11/25/2005		EXAMINER	
BLANK RO			HORWAT, JENNIFER A		
600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037				ART UNIT	PAPER NUMBER
				3737	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		The				
	Application No.	Applicant(s)				
	10/811,887	ASHTON, EDWARD				
Office Action Summary	Examiner	Art Unit				
	Jennifer Horwat	3737				
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a rep. If NO period for reply is specified above, the maximum statutory period. - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be till be within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE.	mely filed ys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on 30 № This action is FINAL. 2b) Thi Since this application is in condition for allowed closed in accordance with the practice under	s action is non-final. ance except for formal matters, pr					
Disposition of Claims						
4) Claim(s) 1-28 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) 1-28 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o	awn from consideration.					
9)☐ The specification is objected to by the Examiner.						
10) ☑ The drawing(s) filed on <u>3/30/2004</u> is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document * See the attached detailed Office action for a list 	nts have been received. nts have been received in Applica prity documents have been receiv au (PCT Rule 17.2(a)).	tion No red in this National Stage				
Attachment(s)	∧ □ I=1	(DTO 412)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summar Paper No(s)/Mail [Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 6/10/2005.	5) Notice of Informal 6) Other:	Patent Application (PTO-152)				

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 6/10/2005 is in compliance with 37 CFR 1.97-1.98 and all references therein have been considered.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites the limitation "wherein the gradient-descent energy minimization" in the claim. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 16 was intended to be dependent on claim 15 instead of claim 11 which would resolve the problem of insufficient antecedent basis, and was interpreted as such for purposes of examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1-3, 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin, et al (US 6745066). Lin discloses a method for imaging and identifying a region of interest in medical images which includes receiving image data into a computing device (figure 1), receiving an identification of plasma region of interest (claim 1) in which a value is calculated for each voxel (col 6, line 19) using slope (col 6, line 16), peak value (col 5, line 55), and conformance to a gamma variate curve (col 6, line 13) at time of maximum uptake (col 5, lines 26-30) in order to determine inclusion in region of interest. The intensity values are determined at the time at which the contrast agent is at maximum concentration and is calculated using a time0density curve (col 5, lines 15-20). Optionally, the region may be input manually by a user (figure 3, step 132). The device for identifying the region of interest includes an input for receiving image data (figure 1, element 50), a region-identifying device (figure 1, element 78), and a computing device (figure 1, element 110), which carry out the steps of the method previously discussed. A pointing device is inherent in the fact that the "diagnostician draws a circle around an artery in the reference slice" (col 7, lines 19-21) in the user input step, as either a computer mouse, the diagnostician's finger, or other known pointing device would be inherently required to allow the diagnostician to delineate the region of interest.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 9-13, 17-23, and 27-28 are rejected under 35 U.S.C. 103(a) as being 7. unpatentable over Lin in view of Rijpkema, et al ("Method for Quantitative Mapping of Dynamic MRI Contrast Agent Uptake in Human Tumors"). Lin, as discussed above, discloses a method and device for automatically identifying a region of interest for blood flow imaging using optimization methods and for those elements not previously discussed also teaches correcting for inter-frame motion (figure 3, step 130). However, Lin fails to disclose using the method to estimate a volume transfer constant between blood plasma and extra-vascular extra-cellular space. Rijpkema discloses a method for quantitative mapping of dynamic MRI contrast agent uptake in human tumors which includes receiving image data, identifying tumor margins (page 459, results), determining uptake curves (page 459, results), and estimating the volume transfer constant, k_{trans}, from the data (page 458). Additionally, Rijpkema discloses forming an image representing the volume transfer constant, as seen in figure 2b. Claims 9-13 teach the method steps, as set forth above, and the structures in claims 19-23 required for computing the necessary calculations are considered inherently taught by the disclosure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device as disclosed by Lin with the teachings of

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Rijpkema, as Rijpkema discloses a specific use, namely volume transfer constant estimation, of the more general method for blood perfusion study disclosed by Lin, which would benefit from the automation and motion correction additionally disclosed by Lin to provide a more accurate and faster image representation.

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- 8. Claims 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin and Rijpkema as applied to claims 11 and 21 above, respectively, and further in view of Gilhuijs, et al (US 6112112). Rijpkema, as discussed above, discloses identifying tumor margins in the image data, however fails to disclose that the margins are determined through geometrically constrained region growth. However, Gilhuijs teaches an automated method for "assessment of tumor extent in MR images" (col 4, lines 23-24) that uses volume growing to generate the extent of the tumor. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device as disclosed by Lin and Rijpkema with the teachings of Gilhuijs to provide a more "accurate quantification of the shape and extent" (col 1, lines16-17) of the tumor.
- 9. Claims 15, 16, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin and Rijpkema as applied to claims 10 and 20 above, and further in view of Kirk, et al (US 5329478). Lin and Rijpkema, as discussed above, substantially disclose the invention as claimed. Rijpkema discusses solving for the volume transfer constants, as shown on page 458, using the "Larson model" implemented in a Matlab routine which computes in 2 hours, but fails to disclose solving for the constants through gradient-descent energy minimization. However, Kirk teaches

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that "one common approach to optimization is gradient descent" and that an "annealing style" of optimization, wherein the gradient optimization process repeats from each subsequent step, which will prevent the process from stopping at local minima while descending to the global minimum of the function. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a gradient-descent energy minimization to solve the volume transfer constant equation, as it is advantageous to avoid local minima and use a method that ensures a global minimum.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mistretta and Brady teach methods of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah 11/21/05

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